

§ 803.33

- (4) Contact person;
- (5) Contact person's telephone number;
- (6) Date the user facility became aware of the event (month, day, year);
- (7) Type of report (initial or followup (if followup, include report number of initial report));
- (8) Date of the user facility report (month, day, year);
- (9) Approximate age of device;
- (10) Event problem codes—patient code and device code (refer to FDA “Coding Manual For Form 3500A”);
- (11) Whether a report was sent to FDA and the date it was sent (month, day, year);
- (12) Location, where event occurred;
- (13) Whether report was sent to the manufacturer and the date it was sent (month, day, year); and
- (14) Manufacturer name and address; if available.

§ 803.33 Annual reports.

(a) Each user facility shall submit to FDA an annual report on FDA Form 3419, or electronic equivalent as approved by FDA under §803.14. Annual reports shall be submitted by January 1 of each year. The annual report and envelope shall be clearly identified and submitted to FDA with information that includes:

- (1) User facility's HCFA provider number used for medical device reports, or number assigned by FDA for reporting purposes in accordance with §803.3(ee);
- (2) Reporting year;
- (3) Facility's name and complete address;
- (4) Total number of reports attached or summarized;
- (5) Date of the annual report and the lowest and highest user facility report number of medical device reports submitted during the report period, e.g., 1234567890-1995-0001 through 1000;
- (6) Name, position title, and complete address of the individual designated as the facility contact person responsible for reporting to FDA and whether that person is a new contact for that facility; and
- (7) Information for each reportable event that occurred during the annual reporting period including:
 - (i) User facility report number;

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- (ii) Name and address of the device manufacturer;
 - (iii) Device brand name and common name;
 - (iv) Product model, catalog, serial and lot number;
 - (v) A brief description of the event reported to the manufacturer and/or FDA; and
 - (vi) Where the report was submitted, i.e., to FDA, manufacturer, distributor, importer, etc.
- (b) In lieu of submitting the information in paragraph (a)(7) of this section, a user facility may submit a copy of FDA Form 3500A, or an electronic equivalent as approved under section 803.14, for each medical device report submitted to FDA and/or manufacturers by that facility during the reporting period.
- (c) If no reports are submitted to either FDA or manufacturers during these time periods, no annual report is required.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4120, Jan. 26, 2000]

Subpart D—Importer Reporting Requirements

SOURCE: 65 FR 4120, Jan. 26, 2000, unless otherwise noted.

§ 803.40 Individual adverse event reporting requirements; importers.

- (a) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by §803.42 on FDA form 3500A as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.
- (b) An importer shall submit to the manufacturer a report containing information required by §803.42 on FDA form 3500A, as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or